



DRUG TEST INFORMATION

***For
HRP-Certified
Individuals
and
HRP Candidates***

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Contents of this brochure are based on 10 CFR Part 712, Human Reliability Program; however, the information presented herein in no way supersedes or has precedence over the provisions of that regulation as published or amended.

Introduction

The Department of Energy (DOE) Human Reliability Program (HRP) is a security and safety reliability program designed to ensure that individuals who occupy positions affording access to certain materials, nuclear explosive devices, facilities, and programs meet the highest standards of reliability and physical and mental suitability.

A system of continuous evaluation helps to identify individuals whose judgment and reliability may be impaired by physical or mental/personality disorders, alcohol abuse, use of illegal drugs or the abuse of legal drugs or other substances, or any other condition or circumstance that may be of a security or safety concern.

The drug testing requirements are integral to the HRP. They serve to identify those who use illegal drugs or abuse other medications and also help to deter the use of these substances. The regulations that govern HRP drug testing are Executive Order 12564 and DOE Order 3792.3, “Drug-Free Federal Workplace Testing Implementation Program,” for federal employees, and 10 CFR Part 707 for contractor employees. The tests are conducted under the *Mandatory Guidelines for Federal Workplace Drug Testing Programs* promulgated by the Substance Abuse and Mental Health Services Administration (SAMHSA) of the Department of Health and Human Services (HHS). These guidelines establish scientific and technical requirements for drug testing programs and standards for certification of laboratories that process the samples and report the results. They also stipulate the responsibilities and qualifications of the medical review officer (MRO) who reviews the results of the drug test and reports them to the agency or contractor.

The information provided in this booklet is based on the SAMHSA guidelines and the HRP requirements, however the information presented herein in no way supersedes or has precedence over the provisions of either, as published or amended.

HRP drug testing

Drug testing is conducted initially as part of the HRP certification requirements. It is then performed randomly, at least once in every 12-month period from the previous drug test. Drug tests are also performed if an individual is involved in an incident, unsafe practice, occurrence, or based on reasonable suspicion.

The *Mandatory Guidelines*, which govern all federal drug testing programs, require that the tests be performed for marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP). This panel of drugs is sometimes called the “SAMHSA 5.” For cause and reasonable suspicion, the test panel can include all drugs on Schedules I and II of the Controlled Substances Act. Urine specimens collected for drug testing may not be used for any other analysis or test.

Random testing

The 12-month random testing period begins with the day of the initial drug test conducted for HRP certification. A drug test will be required at least once during the 12 months following the initial test period. A mathematical formula called “random selection with return” ensures that this cycle is maintained and that selection is truly random. After testing, each individual is returned to a group that is eligible to be tested again. This system allows a certain percentage of individuals to be tested more than once during the 12-month period.

Refusal to submit

The HRP requires an individual who has been notified of selection for drug testing to report to the collection facility within two hours, but *individual facilities may establish a shorter amount of time*. Those who fail to report within the required time are considered to refuse to submit to testing, which automatically results in a positive finding. Conduct that obstructs the testing process and failure to cooperate with the technician are other circumstances that also constitute refusal to submit to testing and result in a positive finding.

Collection procedures

Collection sites are required to be secure, ensure specimen identity and integrity, and be furnished with all necessary personnel, materials, and equipment. Unless there is reason to believe that a particular donor may alter or substitute the specimen being provided, the specimen collection site allows individual privacy. If there is any reason to believe that a specimen may have been altered or substituted, another specimen will be obtained under direct observation. No unauthorized personnel are permitted in the collection site when urine specimens are collected or stored.

For each urine specimen, the collector completes a chain-of-custody form, which outlines and documents steps that are performed to correctly identify the donor of the specimen, to ensure that a specimen has not been diluted, adulterated, or substituted, and to protect its integrity.

After collection, the donor initials a tamper-evident seal that certifies that the specimen was collected from him or her. The specimen is then safeguarded in temporary storage until it is shipped to the laboratory for testing. The specimens are packaged to minimize damage during shipment, and the shipping containers are securely sealed to detect tampering.

Laboratory procedures

The Mandatory Guidelines stipulate that all laboratories that process specimens for a federal agency’s drug-free workplace program be certified. This ensures the accuracy and quality of laboratory results. All personnel are required to be qualified and have the skills and training necessary to perform the tasks assigned.

Laboratories are secure at all times, with access limited to authorized individuals and escorted visitors. Chain-of-custody procedures are used to maintain control and accountability of specimens—from receipt, through testing and reporting of results, to storage and final disposition of specimens.

Initial test. The initial drug test uses an immunoassay technique that identifies metabolites* of the five classes of drugs. A metabolite level below the level established by HHS indicates the specimen is negative. If the metabolite level is above the specified level, the specimen is identified as positive and will be tested again using a different method.

Confirmatory test. When the initial test identifies a sample as positive, a confirmatory test is performed. An analytical technique is employed using gas chromatography (GC) to separate the components of a mixture and mass spectroscopy (MS) to characterize each of the components individually. The GC/MS method can both qualitatively and quantitatively evaluate a solution, such as urine, that contains a number of chemicals.

The laboratory reports all non-negative results for a specimen. For example, if a specimen is positive for a marijuana metabolite, a cocaine metabolite, and an adulterant, all three results will be reported. Unless validity test results indicate that the specimen may not be valid, specimens that test negative on the confirmatory test are discarded.

Validity test. Every specimen is tested in the laboratory to ensure that it is a valid specimen. These tests determine abnormalities in the specimen including creatinine concentration, pH, and oxidizing adulterants. If abnormal physical characteristics are noted, additional validity tests are performed.

Test results

The test results are certified correct by a certifying scientist, and then all drug test results, both negative and positive, are reported directly to the MRO within about five working days after the specimen is received. For positive tests, the positive result is reported along with the specific drug that is indicated. Specimens found to be adulterated or substituted are reported as such and the numerical values that support the finding are provided.

Results are transmitted to the MRO by various electronic means or by fax, courier, or mail in a manner designed to ensure confidentiality of the information. Results are not provided verbally by telephone. The security of the laboratory's data transmission is ensured and access to the transmission, storage, and retrieval systems is limited. For positive tests, a legible copy of the chain of custody form is also transmitted.

* Compounds that result from the body's metabolism of the substance.

Storage of specimens

All positive, adulterated, substituted, and invalid urine specimens are frozen in long-term storage for a minimum of one year so that they will be available for retesting if necessary. An agency may request that the laboratory retain the specimen for an additional period of time, but if no such request is received, the specimen is destroyed at the end of the one-year period.

Quality assurance and control

All certified drug testing laboratories have stringent quality assurance and control programs that govern and monitor all aspects of the laboratory process. The quality assurance and control process includes, but is not limited to, specimen access, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrations and controls, and validation of analytical procedures. Unsatisfactory performance tests are investigated and can cause the laboratory to lose its testing certification.

Review procedures

An essential component of drug testing programs is the MRO review of each test result before it is communicated to the agency. The MRO is a licensed physician with knowledge and experience in substance abuse disorders and detailed knowledge about the possible medical explanations for positive drug test results and issues regarding adulteration and substitution. The MRO has no financial or other interest in the laboratory for which tests are being reviewed.

MRO review is necessary because a positive test result does not automatically identify the donor as an illegal substance user. Likewise, a specimen that is identified as adulterated, substituted, or invalid does not necessarily mean that the sample has been tampered with. For positive results, the MRO interviews the donor to determine if there is a valid medical explanation, and the donor's medical records may be requested to determine if the result could have resulted from a legally prescribed medication. If the MRO determines that there is a legitimate medical explanation for a positive result, the test will be reported as negative and no further action will normally be taken. For invalid results, the MRO may require testing by another HHS-certified laboratory. In some cases, a directly-observed collection may be required. The donor may ask that results found to be positive, adulterated, or substituted be tested by a second laboratory. This request must be made within 72 hours of being notified by the MRO. The individual shall bear the costs of transportation and/or testing of the specimen.

Final results

The MRO reports the final results of all tests in writing in a manner that ensures the confidentiality of the information. No numerical values are released. The records are maintained and used with the highest regard for privacy, and all urinalysis results are covered by the Privacy Act. Employees who are subject to drug tests

have access to their test results upon written request. Records relating to HHS laboratory certification, review, or revocation of certification are also available.

Consequences

The HRP requires that individuals who test positive be immediately removed from HRP duties and that DOE personnel security be notified. Because involvement with illegal drugs is a security concern as defined in 10 CFR §710.8(k), the individual's access authorization will be adjudicated under 10 CFR 710, "General Criteria and Procedures for Determining Eligibility for Access to Classified Matter or Special Nuclear Material."

Glossary

Adulterated Specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Chain of Custody. Refers to the process used to document the handling and storage of a specimen.

Confirmatory Drug Test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Confirmatory Validity Test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

GC/MS. A highly accurate instrument using a combination of gas chromatography (GC) and mass spectrometry (MS) to provide qualitative and quantitative results for confirmatory drug tests.

Initial Drug Test (also known as Screening Test). An immunoassay test to eliminate “negative” urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Initial Validity Test. The first test used to determine if a urine specimen is adulterated, dilute, or substituted.

Invalid Result. Refers to the result reported by a laboratory for a urine specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Medical Review Officer (MRO). A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's test result together with his or her medical history and any other relevant biomedical information.

Non-Negative Specimen. A urine specimen that is reported as adulterated, substituted, positive for a drug or drug metabolite, or invalid.

Specimen. The portion of urine that is collected from a donor.

Substituted Specimen. A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.



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